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10/591,582

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EXAMINER

FLOOD, MICHELE C

ART UNIT

PAPER NUMBER

1655

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/591,582	Applicant(s) LELOUARN, CLAUDE	
	Examiner Michele Flood	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on September 24, 2008.

Claims 1-10 are under examination.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, as amended, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating or reducing hair growth in a patient suffering hirsutism comprising administering an effective amount of botulinum toxin A to said person in need thereof, does not reasonably provide enablement for a method of reducing hair growth in person with hypertrichosis or in a person suffering from hirsutism comprising the administration of any and all amounts of any and all types of botulinum toxins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant's arguments have been fully considered but rendered moot due to the amendment of the claims. Therefore, the rejection stands for the reason set forth in the previous Office action but slightly amended to address the amendment to the claims.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2D 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

Nature of the Invention. The claims are drawn to a method for treating of reducing hair growth in a person with hypertrichosis or in a patient suffering from hirsutism comprising administering a botulinum toxin to said person or patient. The claims are further drawn to a method wherein the botulinum toxin is a botulinum toxin of type A, B or F.

Breadth of the Claims. The claims are broad in that the claims are drawn to a method of reducing hair growth in a person with hypertrichosis or in a patient suffering from hirsutism comprising administering any and all types of botulinum toxins in any and all amounts and/or a method of reducing hair growth in a person with hypertrichosis or in a patient suffering from hirsutism comprising administering any and all amounts of botulinum toxin of A, B or F. The complex nature of the subject matter of the invention is clearly exacerbated by the breadth of the claims.

Guidance of the Specification and Existence of Working Examples. Applicant has reasonably demonstrated a method of reducing downy hairs on the upper lip of a

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patient seeking hair growth treatment comprising administering a solution containing 3 units of BOTOX™ (Allergan, France; Botulinum toxin type A) to several points of the epidermis situated just above the red of their upper lip. For example, on page 4 of the present specification under “EXAMPLE”, Applicant discloses that such administration presented less downy hair on the upper in a follow-up observation, four months later. Given the foregoing, it appears that Applicant has demonstrated a method of treating hirsutism comprising administering an effective amount of a pharmaceutical composition comprising botulinum toxin A via injection to the upper lip of a person in need thereof wherein the administering of the claim-designated pharmaceutical composition reduced downy hairs on the upper lip of the treated person, given that the presence “downy hairs” on the upper lip of a patient is often associated with hirsutism whereas hypertrichosis is generally characterized by the presence of vellus, “downy hairs” growing evenly over the body. However, nowhere in the originally filed specification has Applicant demonstrated a method of reducing hair growth in a person with hypertrichosis or in a person suffering from hirsutism comprising the administration of any and all amounts of any and all types of botulinum toxins or a method of reducing hair growth in a in subjects with either hypertrichosis or hirsutism comprising the administration of any and all amounts of botulinum toxin of type A, B or F, as broadly claimed by Applicant.

Predictability and State of the Art. The state of the art at the time the invention was made was unpredictable and underdeveloped. It should be noted that the state of the art at the time of filing of the present specification suggests that the delivery of

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cosmetics or pharmaceuticals comprising botulinum toxin for the prevention of hair growth in subjects teaches away from the instantly claimed methods of treatment since Maurer (US 200210028765 A1) teaches a process for improving hair growth in humans comprising the injection of botulinum toxin to subjects.

The claims broadly recite the administration of a botulinum toxin or a botulinum toxin of any of type A, B or F to either a person with hypertrichosis or a patient suffering with hirsutism. However, the claims are not enabled for the administration of any types of botulinum toxin to any and all parts of the body in any all and all amounts. The administration of any effective amount of a botulinum toxin A within the skin at or near the medulla, brain stem, pons, cerebellum and cerebrum would effectively induce paralysis, and even death.

As Clostridial toxins, of which botulinum toxin A is a member, are among the most toxic substances known for man and have caused blurred vision, dry mouth, constipation, dizziness, abdominal cramps, nausea/vomiting, general weakness, apathetic behavior, orthostatic hypotension, impaired micturition/sexual function, muscle paralysis (US Pat. 5,562,907, col. 1, lines 35-37) and death, complications due to apparent diffusion of the toxin from the infected muscle(s) to adjacent muscles resulting in difficulty in swallowing, stomach feeding, resulting in paralysis (see Pat. 5,562,907, col. 5, lines 38-65 and col. 6, lines 1-14) and toxin leakage induced edema, serum albumin decrease and injury to vascular endothelium (see col. 8, lines 45-65), the local administration of any amount of botulinum toxin A to any skin location of a mammal, would not serve to treat or prevent a skin disorder.

There is no guidance in the specification, other than the aforementioned example directed to the administration of an effective amount of botulinum toxin A for reducing the hair growth of downy hairs in a patient. Accordingly, in view of the breadth of the claims, the lack of guidance provided by the specification, the lack of working examples, and the lack of correlative working examples, as well as the unpredictability of the art, it would take undue experimentation without a reasonable expectation of success for the skilled artisan to make and/or use the instantly claimed method, as broadly claimed by Applicant.

Claim 10, as amended, remains rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treating or reducing hair growth in a patient suffering hirsutism comprising administering an effective amount of botulinum toxin to said person in need thereof, does not reasonably provide a cosmetic treatment intended to prevent hair growth in a pet comprising administering an effective quantity of botulinum toxin.

Applicant argues that the amendment to the claim overcomes the rejection because the claim has been amended to recite either "treatment or reduction". However, no such amendment was made to Claim 10. Therefore, Applicant's are moot; and, therefore Claim 10 stands rejected for the reason clearly set forth in the previous Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied as necessitated by amendment.

The metes and bounds of Claims 1-3 and 6 are rendered vague and indefinite by "treating" or "treats" or "treat" because it is uncertain as to what is the subject matter to which any of the terms encompass, given that no functional effect is associated with to provide a result-effect for any of the terms. For instance, it is unclear as to what result is effected when the claim-designated ingredient of botulinum is administered to a subject to treat hair growth. For example, does the treating reduce hair growth, increase hair growth or inhibit growth, increase or decrease hair density, or increase the diameter of hair follicles? Or, does the administering of the neurotoxin provide a method of treatment for increasing shine of hair or prevent hair breakage? The lack of clarity renders the claims ambiguous.

The term "effective quantity" in Claim 6 is a relative term which renders the claim indefinite. The term "effective "quantity" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The amount that is administered is considered to be effective, but what it is effective for is not distinctly claimed.

Claim 10 recites the limitation "The cosmetic treatment" in line 1. There is insufficient antecedent basis for this limitation in the claim. Applicant may overcome the rejection by replacing "The" with A.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-8, as amended, are rejected under 35 U.S.C. 102(b) as being anticipated by Donovan (A*). Newly applied as necessitated by amendment.

Applicant claims a method for a cosmetic treatment method intended to treat or reduce hair growth in a person wanting such a treatment comprising administration. to an area to be treated, of a pharmaceutical composition including botulinum toxin in an effective quantity. Applicant further claims the cosmetic treatment method according to claim 6, wherein the botulinum toxin is a botulinum toxin of type A, B, or F. Applicant further claims the cosmetic treatment of claim 7, wherein the botulinum toxin is a botulinum toxin of type A.

Donovan teaches administering an effective amount of botulinum toxin type A to a 5-year-old female diagnosed with precocious puberty characterized by development of pubic hair (read herein as a person in want of a cosmetic method intended to treat or reduce hair growth). Donovan teaches that administration of an effective quantity of the neurotoxin agent to the patient reduced signs of puberty.

The method taught by Donovan is not expressly taught as a cosmetic treatment intended to treat or reduce hair growth in a person wanting such a treatment. However, the instantly claimed method is a one-step process for the administration of an effective quantity of botulinum toxin to an area to be treated, wherein the administering of the botulinum toxin provides a cosmetic treatment method intended to treat or reduce hair growth in a person in want of such treatment. Therefore, a cosmetic treatment intended to treat or reduce hair growth in a person wanting such a treatment is deemed inherent to the Donovan' method, especially given that Donovan teaches that the botulinum toxin was effective in ameliorating symptoms of puberty (read herein as including the development of unwanted pubic hair) in the patient.

The reference anticipates the claimed subject matter.

Claims 6-9, as amended, are rejected under 35 U.S.C. 102(b) as being anticipated by Kinkelin et al. (U). Newly applied as necessitated by amendment.

Applicant's claimed invention of Claims 6-8 was set forth above. Applicant further claims the cosmetic treatment method according to one of claims 6 to 8, wherein the composition is applied to an area of the body including the torso, legs, the arms, the

armpits or the face.

Kinkelin teaches a method of administering botulinum A to the forehead (read herein as the face).

The method taught by Kinkelin is not expressly taught as a cosmetic treatment intended to treat or reduce hair growth in a person wanting such a treatment. However, the instantly claimed method is a one-step process for the administration of an effective quantity of a pharmaceutical composition including botulinum toxin to an area to be treated, wherein the administering of the botulinum toxin provides a method intended to treat or reduce hair growth in a person. In the instant case, the method taught by Kinkelin comprises administering one and the same ingredient to the face of a person. Therefore, a cosmetic treatment intended to prevent hair growth in a pet is deemed inherent to the Kinkelin' method.

The reference anticipates the claimed subject matter.

Claims 6-8, as amended, are rejected under 35 U.S.C. 102(b) as being anticipated by Schwartz et al. (B*) and Maurer (US 2002/0028765 A1). Newly applied as necessitated by amendment.

Applicant's claimed method was set forth above.

Schwartz teaches a method of administering an effective amount of botulinum toxin A to a person in want of a cosmetic treatment intended to treat hair growth.

Maurer teaches a method of administering an effective amount of botulinum toxin A to a person in want of a cosmetic treatment intended to treat hair growth.

The references anticipate the claimed subject matter.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele Flood
Primary Examiner
Art Unit 1655

MCF
December 12, 2008

/Michele Flood/
Primary Examiner, Art Unit 1655